

## DEPARTMENT OF HEALTH SERVICES

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September 10, 1999

State Water Resources Control Board, Division of Water Quality  
Attention: Mr. Todd Thompson, Associate Water Resources Control Engineer  
P.O. Box 944213  
Sacramento, CA 94244-2130

Re: Written Comments on "Draft Environmental Impact Report (DEIR) for General Waste Discharge Requirements for Biosolids Land Application"

The California Department of Health Services submits the following comments to assist the State Water Resources Control Board (SWRCB) in the development of the Environmental Impact Report for General Discharge Requirements for Biosolids Land Application.

General Comments:

1. We understand that the DEIR exclusively addresses the use of biosolids (municipal waste), and that waste from farm operations is outside the scope of developing this DEIR. However, from the viewpoint of public health, the final use of biosolids regardless of whether it comes from the municipality or from the farm may be the same agricultural field. And the field is the source of the problem, not whether the waste came from a municipality or from a farm. Since a large proportion of what is considered in this DEIR applies to farm waste as much as it does to municipal waste, we suggest that, if possible, SWRCB consider including waste from farm operations in the DEIR. (As you are aware, the U.S. Environmental Protection Agency and the U.S. Department of Agriculture have proposed waste management regulations for discharge of waste from large farm operations).

2. We think that the comparison of human disease incidence between high biosolids application counties with low biosolids application counties was improper, and may have led to an inaccurate conclusion in the DEIR with regard to the public health risk from use of biosolids. As clearly described in the DEIR, the pattern of use of biosolids has changed dramatically over the last few years. Any comparison to health data would have to account for this. In addition and most importantly, the hypothesis that living in higher use counties conveys a higher public health risk implies that consumption of agricultural products, water, or for that matter air, (i.e.: exposure) is also higher risk in those counties; an unrealistic assumption. We believe that human disease incidence data is not a good way to assess the true risk from use of biosolids.

Written Comments on DEIR for GWDR for Biosolids Land Application  
Page 2

3. Human disease incidence surveillance systems are by definition a posteriori, that is, the person has already become sick. A good case control study that identifies exposure factors, together with new molecular typing technology might be able to traceback a specific outbreak of disease to a common source at a given field or even to the contents of the biosolids applied to a given field if we have the source data on record. After a few years we could also correlate monitoring data with ground water quality data. This is why it would be good to have continuous monitoring data available. The proposed 3-year period seems reasonable.

Specific Comments:

(1) DEIR, Chapter 5, Page 5-21:

Under the heading "Food Safety", the DEIR listed several federal laws that apply to the quality and safety of foods: Federal Food, Drug and Cosmetic Act (21 U.S.C. 301), Unavoidable Contaminants in Food and Food Packaging Material (21 CFR 109), Food labeling and Processing (21 CFR 100-199), and Good manufacturing Practices (21 CFR 110), etc. The list, however, did not include state laws which adopt the federal regulations and contain additional requirements for the safety of foods. We suggest that two state laws be added to the list: the California Health and Safety Code, Division 104, Part 5 (Sherman Food, Drug, and Cosmetic Law) and the California Uniform Retail Food Facilities Law (CURFFL; Health and Safety Code Sections 27500, et seq.).

The DEIR list of federal laws includes the "Model Food Code" as one of applicable food safety-related regulations. The Model Food Code is not a regulation, but a federal recommendation for adoption by states. California does not adopt the entire Model Food Code. CURFFL is substantially equivalent to it, and contains most of its food safety-related features. We suggest that the "Model Food Code" be deleted from the list and be replaced by CURFFL.

(2) DEIR, Appendix A (Draft Text of the General Order), Page 22, Item 17:

The draft text of the General Order, Item 17 states that "The discharger shall report any noncompliance which may endanger human health or the environment. Any such information shall be provided orally to the RWQCB's executive office within 24 hours from the time the discharger become aware of the circumstances. . . .Also, the discharger shall notify the Office of Emergency Services (1-800-852-7550) and the local health department as soon as practical but within 24 hours after the incident." DHS's Food and Drug Branch (FDB) is responsible for the safety of food products harvested from cropland in California including those harvested from land to which biosolids have been applied. Thus, it is essential for FDB to receive the information of non-compliance which may endanger human health as quickly as possible, assess the safety of the resultant food products, and take appropriate action. We suggest that the last sentence of the Item 17 be changed to read ". . . Also, the discharger shall notify the Office of Emergency Services (1-800-852-7550), the State Department of Health Services"

Food and Drug Branch (916-445-2263), and the local health department as soon as practical but within 24 hours after the incident."

4-7  
(Cont)

(3) DEIR, Chapter 5, Page 5-1

In the first paragraph, we suggest that the second sentence be changed to read "Pathogens (or pathogenic organisms) are disease-causing organisms, including certain bacteria, parasites, and viruses."

4-8

(4) DEIR, Chapter 5, Page 5-3

In the first paragraph, the term "emerging pathogens" must be defined as this term is used inconsistently throughout the document. Many pathogens are considered to be emerging pathogens including *E. coli* O157:H7 and *Cyclospora* which have caused several outbreaks in California. This paragraph seems to limit the definition of emerging pathogens only to new, formerly unidentified organisms which is the rare situation. The current definition of emerging pathogens is "New, reemerging or drug-resistant infections whose incidence in humans has increased within the past two decades or whose incidence threatens to increase in the near future" (Emerging Infections: Microbial Threats to Health in the United States, Institute of Medicine, 1992). Please make appropriate changes to reflect the broader, commonly known definition of an emerging pathogen.

4-9

At the bottom of the first paragraph please add to the examples for importation of diseases into California, "(for example, by travelers or by importation of contaminated food or animals)."

4-10

(5) DEIR, Chapter 5, Page 5-4

Please make to following changes to the second paragraph:  
"Tables 5-1 through 5-4 list...host organisms, the infective dose, and provides..."

4-11

"The infective dose for some *Salmonella* serotypes and other pathogenic...organisms can multiply in high numbers..." The infective dose for *Salmonella* sp. varies by serotype and host factors.

(6) DEIR, Chapter 5, Table 5-1

Please correct the number of types of *Salmonella* on the left column to read "*Salmonella* (≥2000 types)."

4-12

(7) DEIR, Chapter 5, Table 5-3

Please add *Cyclospora* to the list of human pathogens.

4-13

(8) DEIR, Chapter 5, Page 5-5, Emerging pathogens of concern

This entire paragraph is misleading because it implies that the cause of many disease outbreaks is a new or unidentified pathogen. In the majority of outbreaks a single or small list of organisms is suspected as a cause. It must be emphasized that the reason why there is no confirmation of the pathogen causing the outbreak is due to 1) the patient not seeking medical attention, 2) no laboratory diagnostic tests (including stool cultures and examination) being performed, and 3) either late or non-reporting of illnesses hindering the investigation of individual cases or outbreaks. While the majority of outbreaks are due to bacterial causes, limitations on our diagnostic capabilities may also hinder our ability to confirm a diagnosis. This section needs to be expanded to discuss these limitations of the data. In addition, please expand this section to include the numerous sporadic cases and not limit the section to outbreaks only. As mentioned previously, please expand the definition of "emerging pathogens" to include a broader number of diseases currently considered to be emerging or re-emerging.

4-14

The term "unknown origin" should be replaced with either an "unknown cause" or "unknown source" depending upon whether the causative agent or the source of infection is being referred to.

4-15

(9) DEIR, Chapter 5, Page 5-6

The second paragraph references table 5-5 and attempts to compare the number of reported illness to the quantities of applied biosolids. This comparison is very misleading and inappropriate since there are many other factors involved such as population, demographic, and geographic effects. It is impossible to determine the causality or association of disease and quantity of biosolids application by just crudely comparing the numbers. In addition, all of the disease data listed in the table are inaccurate.

4-16

In the third paragraph, please omit "voluntarily" in the sentence regarding disease reporting. Please recalculate all of the disease numbers (throughout the document) and tables to reflect the most current reported numbers of diseases for tables 5-6 through 5-8 and appendix E tables E-1 through E-16. All of the number of reported diseases appears to be grossly underestimated. The actual numbers of reported cases compared to those listed in the tables appears to be at least six times higher. This difference will greatly affect the conclusions and comparisons drawn based upon the inaccurate data.

4-17

Please change "worm" to "helminthes" in the last sentence of the fourth paragraph.

4-18

(10) DEIR, Chapter 5, Tables 5-6 through 5-8

Please contact the Department of Health Services, Surveillance and Statistics Section for the numbers of reported diseases. The numbers presented in these tables are grossly underestimated and do not come close to the actual numbers of disease reports. We are greatly concerned that interpretations of erroneous data will lead to inaccurate conclusions. Population

4-19

data for each county as well as presentation of crude rates of diseases by county (number of cases per 100,000 population) will allow for better comparison of disease incidence between counties.

(11) DEIR, Chapter 5, Page 5-14

In the fourth paragraph, please make the following changes:

"...transmission of disease has been documented in California as it related to biosolids management although the potential exists."

(12) DEIR, Appendix E, Page E-1, Part I. Diseases of Interest

Please omit "voluntarily" in the last paragraph. Please expand to describe how diseases are reported and the problem of under-reporting in California. It has been estimated that only a very small percentage of actually cases are reported to the health department. By focusing only on the numbers of reported cases, the true incidence of disease will be underestimated and this will greatly affect any conclusions drawn.

(13) DEIR, Appendix E, Page E-1, Bacterial Diseases

Please expand the name of "*E. coli* O157" to "*E. coli* O157:H7." Please note that it is the letter "o" before the 157 and not a zero. Please make this change throughout the document. In the first sentence, please replace "guts" with "intestinal tracts."

(14) DEIR, Appendix E, Page E-5

Please add "reptiles" to the list of *Salmonella* animal reservoirs since other reptiles besides turtles and tortoises can be a reservoir for *Salmonella*.

For the third paragraph, please provide a corresponding range of the rates of salmonellosis since a range is given for the number of estimated cases. Please revise the numbers of salmonellosis in California based upon the current numbers of reported cases.

At the end of the fourth paragraph, please convert the *S. typhi* morbidity rate to number of cases per 100,000 population which is a standard format of presenting disease incidence.

(15) DEIR, Appendix E, Page E-11, Ameobiasis

Correct spelling of "amoebiasis" to amebiasis. Please elaborate that none of the cases have been definitively associated with biosolids however, most cases are not investigated to the extent as to make a definitive association. For amebiasis cases in addition to campylobacteriosis, giardiasis, salmonellosis (other than typhoid fever), and shigellosis, only summary counts of cases are reported to DHS and a thorough investigation by the local health department into each case of these diseases is not always conducted.

(16) DEIR, Appendix E, Page E-23, Roundworms

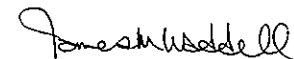
Please change the last sentence to read "This disease occasionally occurs and is not a reportable disease in California."

(17) DEIR, Appendix E, Page E-27, Pathogens of concern

Please include the definition of emerging pathogens in comment (2). Please expand tables E-17 through E-19 to include a comprehensive list of organisms currently considered to be emerging pathogens.

Hopefully, the information provided is helpful to you. If you have questions, please call me or Dr. Chang-Rae Lee at 916-445-2263.

Sincerely,



James M. Waddell, Acting Chief  
Food Safety Section  
Food and Drug Branch

## **Responses to Comments from the California Department of Health Services**

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- 4-1. The similarities between biosolids and animal manures/waste in terms of pathogens is acknowledged. However, the two potentially beneficial materials are different enough in composition to be addressed separately. As mentioned, the U.S. Department of Agriculture and the U.S. Environmental Protection Agency (EPA) are developing management options for animal manures/waste. That approach will most likely be specifically oriented toward the federal program and the type of waste, focusing on different potential environmental impacts.
- 4-2. Human disease incidence data were reported to indicate the relative degree of human disease to areas of biosolids use. This information was not used to draw conclusions regarding the health risk associated with biosolids use. Also see Response to Comment 4-16.
- 4-3. The assumption that there was a greater risk associated with increased biosolids use was not made, nor was a hypothesis to this effect made in the comparisons. Human disease incidence data were used only to determine whether there was any association between counties where biosolids were applied and any greater number of disease cases identified through the current reporting system. A revised set of disease case records and the calculated incidence per 100,000 population by county are presented in Appendix B of this final EIR, a revised version of Appendix E from the draft EIR.
- 4-4. Comment noted. The comment supports development of a study to evaluate human disease incidence utilizing the monitoring data collected by the provisions required under the proposed GO for land application. The provisions of the proposed GO should provide site-specific information that could be used in any future studies. No studies are proposed or recommended by SWRCB staff at this time.
- 4-5. The following items are added to the list of regulations in Chapter 5, page 5-22:
- #      California Health and Safety Code, Division 104, Part 5 (Sherman Food, Drug and Cosmetic Law)
- #      California Uniform Retail Food Facilities Law (CURFFL; Health and Safety Code Sections 27500 et seq.)
- 4-6. The following item is deleted from the list of regulations in Chapter 5, page 5-22:
- #      ~~Model Food Code (42 U.S.C. 243 and 311 and 31 U.S.C. 686 authorities)~~

- 4-7. By contacting the Office of Emergency Services, it was believed that all necessary agencies would receive notification. However, the text of the proposed GO, as found in Provision No. 17 of Appendix A, now reads as follows:

Also, the discharger shall notify the Office of Emergency Services . . . the State Department of Health Services Food and Drug Branch (916/445-2263), . . .

- 4-8. In Chapter 5, page 5-1, the second sentence of the first paragraph has been changed as follows:

Pathogens (or pathogenic organisms) are disease-causing organisms, including certain bacteria, parasites, and viruses.

- 4-9. In Chapter 5, page 5-3, in the second paragraph, the second sentence, “Emerging pathogens are briefly described . . . (there have been no reported disease outbreaks)” has been replaced with the following:

Emerging pathogens are organisms responsible for new, reemerging, or drug-resistant infections whose incidence in humans has increased within the past two decades or whose incidence threatens to increase in the near future. Included are such pathogens as *E. coli* O157:h7 and *Cyclospora*, which have caused several outbreaks in California.

- 4-10. Also on page 5-3 in the second paragraph, the following has been added to the second-to-last sentence:

(for example, by travelers or by importation of contaminated food or animals).

- 4-11. The first full paragraph on page 5-4, starting with the 12th line, has been changed to read as follows:

Tables 5-1 through 5-4 list the specific disease organisms, diseases they cause, host organisms, and the ~~infection~~ infective dose....

With the sentence beginning on line 17, make the following changes:

The infective dose for some ~~salmonellae~~ salmonella serotypes and other pathogenic . . . organisms can ~~increase~~ multiply in high numbers. . . The infective dose for *Salmonella* sp. varies by serotype and host factors.

- 4-12. In Table 5-1, the number of types of salmonella in left column has been changed to (>2,000 types) from (1700 types).

Also in Table 5-1, “infectious” has been changed to “infective” in the heading for the last table column.

- 4-13. The following information has been added to Table 5-3, at the end of the list of human pathogens:

Cyclospora cayetanesis      Cyclosporiasis (severe Diarrhea)      None known

- 4-14. On page 5-5, under “Emerging Pathogens of Concern”, the entire paragraph has been replaced as follows:

In most outbreaks of unknown cause or unknown source, a single or small list of organisms is normally suspected. If the causative agent is not identified or confirmed, it is because (1) the patient not seeking medical attention, (2) no laboratory diagnostic tests (including stool cultures and examination) are performed, and (3) either late or nonreporting of illnesses occurs that hinders the investigation of individual cases or outbreaks. Although most outbreaks are attributable to bacterial causes, limitations on our present diagnostic capabilities may also hinder a confirmatory diagnosis. New techniques using genetic markers and electron microscopy have improved laboratory capabilities to detect and identify pathogens, particularly viruses. There continue to be numerous sporadic cases of diseases (particularly gastroenteritis) of unknown cause or unknown source that arise and may be associated with a number of agents or sources. A literature review of disease outbreaks on a worldwide basis was performed to determine some of the emerging pathogens and their modes of transmission. The results of this search are summarized in Appendix E. The results indicated that the reported cases are normally associated with poor sanitation, poor food preparation and handling practices, or drinking contaminated water. Information on emerging pathogens of concern (bacteria, parasitic microsporidians, viruses, and bovine spongiform encephalopathy) is presented in Appendix E. These are in addition to those pathogens such as *E. coli* O157:h7 and *Cyclospora* that which have caused several outbreaks in California.

- 4-15. See changes made as noted in Response to Comment 4-14.
- 4-16. The comparison of biosolids land application amounts and acreages with the incidence of disease and reported number of cases was presented to determine the relative magnitudes of biosolids use and relate this to disease incidence in counties where land application is greatest. The Department of Health Services’ (DOHS’s) comments are noted; revisions to the text and tables have been made to reflect those comments.

It is clear that many factors are involved in disease rates, such as population, demographic, and geographic effects. However, given the nature of the comments received, reporting of

outbreaks is of interest, particularly in those counties where the use of biosolids is most intense. It is hoped that this information will be helpful to those interested in any particular health-related concerns. It can be used to review trends in reported disease, and the relative magnitude of various illnesses. It is again noteworthy that no evidence has come to light during preparation of this EIR that indicates land application of biosolids can be related to any reported disease case in California.

The disease statistics database has been revisited and revised to reflect the corrected number of reported cases. The requested revisions have been made to Tables 5-6 through 5-8 and Tables E-1 through E-16; and these have been replaced by Tables 5-6a through 5-8a. These tables are provided at the end of the Response to Comments. In addition, new tables numbered 5-6b through 5-8b and Tables E-1b through E-16b have been added to reflect incidence rates per 100,000 people based on population in each county. The time frame for the diseases has been reported for the period 1990 through 1998 where data is available. Note that the reported disease cases are “provisional” for the years 1996 through 1998 according to the DOHS. This means that minor revisions of the reported number of cases are still occurring.

See attached revisions to Tables 5-6 through 5-8, which contain updated and corrected disease statistics summaries ranked by number of cases for the state totals and alphabetically by county for the incidence rates. These tables are labeled 5-6a through 5-8a for the number of cases and 5-6b through 5-8b for the incidence rates.

See Appendix B (formerly DEIR Appendix E) for revised text and tables of the Public Health Technical Appendix that provide detailed year-by-year statistics for disease case numbers and incidence rates based on population.

Revisions to the text starting on paragraph 3 of page 5-6 and ending with paragraph 2 on page 5-7 are as follows:

Data on the diseases of interest (those listed in Tables 5-1 through 5-4) were obtained from the ~~DOHS~~ Department of Health Services (DOHS) (descriptions of the diseases of interest are provided in Appendix E). These data consisted of records on reportable diseases that are ~~voluntarily~~ provided by local county and city health departments (Starr pers. comm.). The diseases for which data were obtained are those with causative agents that could be derived from biosolids; therefore, certain diseases that were rare, not reported, or not related to biosolids were not included (AIDS, fungal diseases, and nonspecific gastroenteritis). The ~~DOHS~~ DOHS information consisted of 46,159 records representing 300,818 cases of disease and covering the period from ~~1991~~ 1990 through 1998 for some diseases and ~~1993~~ 1992 to 1998 for Enterotoxigenic *E. coli* O157:h7 ~~others of more recent origin/or reporting requirements~~. The information was sorted by county, year, and disease (and broken down by pathogenic organisms) and is presented in Tables E-1a and E-1b through E-16

a and E-16b in Appendix E for the number of cases and the incidence rate per 100,000 people by county and summarized on a statewide basis by year in Tables 5-6a and 5-6b. The summary data show that the number of cases of a particular disease and incidence rates ~~varies~~ vary from year to year as conditions favor its occurrence in a particular population.

The incidence of diseases presented on a statewide basis in Table 5-6a are shown by county for the past ~~6 to 8~~ 6-9 years (depending upon when the reporting was started for a particular disease) in Tables 5-7a and 5-7b and 5-8a and 5-8b. Also shown next to each county name (in parentheses) is the county's ranking in the state from the highest (1) to the lowest in terms of the amount of biosolids applied on land in that county in 1998. ~~Table~~ Tables 5-7a and 5-7b contains contain a summary of the bacterial and viral diseases. ~~Table~~ Tables 5-8a and 5-8b summarizes summarize the data on parasitic protozoan and ~~worm~~ helminth diseases that are reported.

As noted in ~~Tables~~ Table 5-5 7 and 5-8, the Central Valley counties of Kern, Merced, and Kings ranked first, second, and third in terms of the amount of biosolids that were land applied. The amounts applied (~~see Table 5-5~~) were 32%, 13%, and 13%, respectively, of the statewide total, or about 58% of the statewide total that was land applied. ~~These three counties had no reported cases of salmonellosis or shigellosis, the two most prevalent bacterial diseases, in 6 years.~~

The comparison of the number of reported outbreaks of acute infectious disease and the listing of counties where biosolids reuse occurs showed no apparent association between the highest biosolids use and any unusual illness outbreaks or patterns. Furthermore, ~~no incidents of acute or chronic disease associated with the use or handling of biosolids were found through examination of these data;~~ discussions with public health officials and a ~~;~~ or review of available literature and discussions with other experts in the field revealed no reported disease problems associated with biosolids land application operations. Again, the types of diseases that might occur are not those that would normally be reported unless it was a severe case involving a visit to a doctor or hospital.

- 4-17. The third paragraph of page 5-6, third sentence is revised by striking out the word “voluntarily”. See Response to Comment 4-16 for information on the revised and expanded presentation of disease data.
- 4-18. In the last sentence of the fourth paragraph on page 5-6, “worm” has been changed to “helminthes”.
- 4-19. See Response to Comment 4-16.



- 4-20. On page 5-14, in the fourth paragraph, the following changes have been made:

No reported cases of airborne transmission of disease ~~were identified~~ have been documented in California as it related to biosolids management although the potential exists.

- 4-21. In Appendix E of the draft EIR, page E-1, Part 1, Diseases of Interest, the last sentence of the paragraph is modified as follows:

The information on disease incidence reflects the data collected by the existing statewide ~~voluntary~~ public health reporting system, in which local health departments (two city and all county health departments) participate. Disease data are reported only for those whose illness results in a visit to a physician or local clinic or hospital and thus represent only a small percentage of the actual cases of illness that may occur. The true incidence of disease from pathogens causing gastroenteritis and other general symptoms normally treated with over-the-counter drugs will be underestimated and thus greatly affect any conclusions drawn from the disease incidence data reported herein.

For this change and many others, see the revised Appendix E, included as Appendix B of this final EIR.

- 4-22. Change the name “*E. coli* 0157” to “*E. coli* O157:H7” in the heading on page E-1 of the draft EIR, in all subsequent text notations, and in Table E-1.

In the first sentence of the third paragraph of page E-1, replace “guts” with “intestinal tracts”.

For this change and many others, see the revised Appendix E, included as Appendix B of this final EIR.

- 4-23. Change the first sentence at the top of page E-5 to read as follows:

...poultry, swine, cattle, rodents, dogs, cats, ~~turtles and tortoises~~ reptiles.

For this change and many others, see the revised Appendix E, included as Appendix B of this final EIR

- 4-24. Regarding Appendix E, page E-5, see the revised Appendix E, included as Appendix B of this final EIR.

- 4-25. Regarding Appendix E, page E-5, see the revised Appendix E, included as Appendix B of this final EIR.

- 4-26. In Appendix E, page E-11, change the spelling of “Amoebiasis” to “Amebiasis”.

For this change and many others, see the revised Appendix E, included as Appendix B of this final EIR

- 4-27. For the requested clarification to and additional changes to Appendix E, page E-23, Roundworms, see the revised Appendix E, included as Appendix B of this final EIR.

- 4-28. The definition of emerging pathogens in Appendix E, page E-27, Pathogens of Concern, was provided and Tables E-17 through E-19 were expanded to include additional organisms considered emerging pathogens.

For the requested clarification and additional changes, see the revised Appendix E, included as Appendix B of this final EIR.